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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/024,932	12/18/2001	Bret Berner	3100-0001.20	5481

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REED INTELLECTUAL PROPERTY LAW GROUP  
1400 PAGE MILL ROAD  
PALO ALTO, CA 94304-1124

EXAMINER

WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/024,932

Applicant(s)

BERNER ET AL.

Examiner

Edward J. Webman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2005.  
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37, 62-71 is/are pending in the application.  
4a) Of the above claim(s) 29-35, 37 and 66-71 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-28, 36 and 62-65 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-25, 36, 62-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Seth et al (US 6,048,547).

Seth et al '547 teach a composition comprising an active ingredient and polyethylene oxide (title). 1-70% active and 1-95% polyethylene oxide is disclosed (column 1 lines 53-55). A hydrophilic active is specified (column 2 line 34). A tablet is disclosed (column 2 line 60). POLYSOX coagulant, the same polymer disclosed by applicants on page 21 line 13, is specified (column 23 example 42). A remarkable delaying effect is disclosed (column 1 line 48). As to the claimed properties, they must be possessed by the anticipatory composition because it is the same as that claimed.

Claims 1-25, 36, 62-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Sako et al. (US 6,562,375).

Sako et al teach composition comprising a drug and polyethylene oxide (abstract). A tablet is disclosed (column 2 line 21). Antibiotics are specified (column 4 line 34). POLYOX 303, the same polymer disclosed by applicants on page 21 line 12-13, is specified (column 4 line 64). A stable preparation is specified (column 1 line 66).

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As to the claimed properties, they must be possessed by the anticipatory composition because it is the same as that claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-28, 36, 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seth et al or Sako et al in view of Grohe et al (US 4,670,444)..

Seth et al and Sako et al are described above. Neither teaches ciprofloxacin.

Grohe et al teaches ciprofloxacin (column 17 example 23). Delivery in tablets is disclosed (column 12 line 46).

It would have been obvious to one of ordinary skill to deliver the composition of Grohe et al in the vehicle of Seth et al or Sako et al to achieve the beneficial effect of a remarkable delaying effect or a stable composition respectively.

Claims 1-28, 36, 62-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Shell et al (US 6,340,475).

Shell et al teach a dosage form designed to be retained in the stomach during the fed mode by swelling. Ciprofloxacin is disclosed (column 7 line 32). POLYOX Coagulant, disclosed by applicants on page 21 line 13, is specified (column 8 line 48). 15-80% drug is disclosed (column 9 line 55). The ratio of drug to polymer is .01:99.99

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to about 80:20 (column 9 lines 51-52). As to the claimed properties, they must be possessed by the anticipatory composition because it is the same as that claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16, 24-25, 28, 36, 62-65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6 of U.S. Patent No. 5,972,389. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims encompass the instant claims regarding the ratio of erosion rate to dissolution rate.


No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, G. Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
EDWARD J. WEBMAN  
PRIMARY EXAMINER  
GROUP 1600